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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,452	06/14/2006	Andreas Lendlein	26538-0016	3000

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HOGAN & HARTSON LLP  
IP GROUP, COLUMBIA SQUARE  
555 THIRTEENTH STREET, N.W.  
WASHINGTON, DC 20004

EXAMINER
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GETTMAN, CHRISTINA DANIELLE

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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10/30/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcpatent@hhlaw.com  
rogruwel@hhlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,452	<b>Applicant(s)</b> LENDLEIN ET AL.	
	<b>Examiner</b> CHRISTINA D. GETTMAN	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 16-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 16-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/16/2008, 08/20/2008</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 16-30, and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase “and/or” in line 2. The phrase “and/or” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention or not.

Claims 1 and 37 recite the phrase “optionally” in lines 4 and 2. The phrase “optionally” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim 3 recites the phrase “wherein the at least one non-shape memory ingredient, wherein the non-shape memory material”. It is unclear from these limitations whether the limitations following the phrase pertain to both the non-shape memory ingredient *and* the non-shape memory material or just one of the two.

Since independent claims 1 and 37 are rejected under 35 U.S.C. 112, second paragraph, their respective dependent claims are rejected as well.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 16, 17, 31, 32-34, 37-39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Phan et al. (U.S. Patent No. 5,603,722). Phan et al. disclose the invention as claimed including a stent (ref. 10) made from a non-metallic SMP (col. 4, lines 44-47), the stent including a non-shape memory ingredient (col. 5, lines 56-col. 6, line 12), the stent having at least one stimuli-triggered shape in memory (col. 4, lines 55-59), the non-shape memory ingredient being one of the recited elements, the SMP material being a thermoplastic, the stimuli being a thermal change or a pH change, and a method of placing the stent in a vessel (col. 7, lines 20 - col. 8, line 3) including placing the stent on a balloon catheter, inserting the stent, expanding the stent, and fixing the stent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. (U.S. Patent NO. 5,603,722). Phan et al. discloses the invention

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substantially as claimed except for the e-module of the SMP material, the reset fixation value of the SMP material, or the reset ratio of the SMP material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an SMP material with the above limitations and the ranges as recited in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 28, 30, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. PHan et al. disclose the invention substantially as claimed except for the SMP comprising a caprolacton unit, pentadecalacton unit, ethyleneglycol unit, propyleneglycol unit, lactic acid unit, glycol acid unit, or combinations thereof. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the SMP material with a caprolacton unit, pentadecalacton unit, ethyleneglycol unit, propyleneglycol unit, lactic acid unit, glycol acid unit, or combinations thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. Phan et al. disclose the invention substantially as claimed except for how the stent is prepared. The claimed phrase "the stent is prepared by" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps.

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Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. Phan et al. disclose the invention substantially as claimed except for removing the stent of claim 1. It would have been obvious to have used the same methods in forming the stent to reduce the size of the stent in the vessel in order for it to be removed. Since the stent can be delivered by using one of the recited stimuli, it would be obvious to use the same stimuli, but in reverse, to remove the stent.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 3:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina D Gettman/  
Examiner, Art Unit 3734  
571-272-3128

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731